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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
UTILITY PATENT APPLICATION TRANSMITTAL

Attorney Docket No.: P-7726
Express Mail No.: **EL 084629739 US**

First Named Inventor or Application Identifier: Derek J. Harper
Title: A Device Used to Connect an External Ventricular Drainage Catheter

CERTIFICATE UNDER 37 CFR SECTION 1.10. I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service, in an envelope address "EXPRESS **EL 084629739 US** addressed to Box Patent Application, Commissioner of Patents and Trademarks, Washington, D.C. 20231, on this April 30, 1998

Juanita I. Traufler
Printed Name

Juanita I. Traufler
Signature

BOX PATENT APPLICATION
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Sir:

We are transmitting the following:

X **Patent Application Transmittal**
X **Specification**
Total Pages: 15 (cover/title page 1 sheet; specification 7 sheets; claims 6 sheets; abstract 1 sheet)
X **Drawings**
Total Sheets: 4 (_ formal; X informal)
_ **Combined Declaration and Power of Attorney:**
- _ Newly executed
- _ Copy from prior application
- _ Deletion of inventor(s) -- signed statement attached deleting inventor(s) named in the prior application (37 CFR 1.63(d)(2) and 1.33(b)
- _ Incorporation by reference -- *The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied above is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference herein.*

_ **Accompanying application parts:**
- _ Notification of filing a _ Continuation _ Divisional _ Continuation-in-Part
- _ Assignment of the invention to Medtronic, Inc.
- _ Assignment cover sheet
- _ Information Disclosure Statement
- _ PTO Form 1449
- _ Copies of IDS citations
- _ Preliminary Amendment
- _ A copy of the Petition or Condition Petition for Extension of Time in the prior application
- X Return postcard

IF A CONTINUING APPLICATION:

_ Continuation _ Divisional _ Continuation-in-Part of prior application no. _.

_ Amend the specification by inserting before the first line the sentence: This application is a _ Continuation _ Divisional _ Continuation-in-Part of application number _ filed _.

_ Cancel in this application original claims _ of the prior application before calculating the filing fee. (At least one of the original independent claims must be retained for filing purposes.)

_ The prior application is assigned of record to Medtronic, Inc.

_ The Power of Attorney in the prior application is to: _.

_ This application claims the benefit of U.S. Provisional Application(s) Serial No. _filed _____.

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FEE CALCULATION

	No. Of Claims Filed	Claims Included in Base Fee	No. Of Extra Claims	Rate	Fee
Total Claims	27	20 =	7	x $ 22	$ 154.00
Independent Claims	5	3 =	2	x $ 82	$ 164.00
Multiple Dependent Claim(s)		0 =		+ $ 270	
Basic Filing Fee			0		$790.00
				TOTAL	**$1108.00**

X Charge Deposit Account No. 13-2546 the sum of $1,108.00 (Filing Fee) and $0 for Assignment recordation fee for a total of **$1,108.00.**

X The Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. 13-2546. A duplicate of this transmittal is enclosed.

April 30, 1998
Date

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PATENT
ATTORNEY DOCKET: P-7726

APPLICATION FOR UNITED STATES LETTERS PATENT

A DEVICE USED TO CONNECT AN EXTERNAL VENTRICULAR DRAINAGE CATHETER

by

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Background of the Invention

1. Field of the Invention

This invention relates to a device for connecting a catheter to tubing for draining excess cerebrospinal fluid from the brain.

2. Description of Related Art

It is common medical practice to drain excess cerebrospinal fluid from the brain in cases of hydrocephelus or trauma to the brain. This is commonly done by inserting a catheter into the ventricles of the brain by a process called a ventriculostomy. The catheter is typically made of silicone. An example of such a catheter is the model 46118 EDM Ventricular Catheter sold by Medtronic-PS Medical of Goleta, California. Excess cerebrospinal fluid is drained through the catheter into a flexible drip assembly line where it is collected and measured in a drip assembly system.

The catheter is connected to the drip assembly line outside the skull of the patient away from the opening placed in the skull for the catheter to pass. An example of such a drip assembly is the model 46128 Becker EDMS Assembly External Drainage and Monitoring System sold by Medtronic-PS Medical of Goleta, California.

As shown in Figure 1, to fix the catheter 2 to the patient's skull, the catheter 2 is typically connected to the drip assembly line 4 of the drip assembly 6 through a luer connector 8 that extends a distance into an inner lumen 10 of catheter 2. The luer connector 8 has an axis 12 that is aligned with the axis 14 of the catheter 2. A silicone "collar" 16 is wrapped around the silicone catheter 2. A portion of the luer connector 8 extends into the catheter 2. Collar 16 is sutured to the patient's scalp 18. The stickiness

of the two silicone pieces, catheter 2 and collar 16, keeps the catheter 2 from moving relative to the collar 16.

The axis 12 of luer connector 8 may run parallel to the patient's scalp 18 making it difficult to connect the drip assembly line 4 to the luer connector 8. This problem occurs because there is no clearance between the luer connector 8 and the patient's scalp 18. In addition, because there are separate elements for luer connector 8 and collar 16, additional time is required to separately configure the luer connector 8 and collar 16. Further, these types of prior art connectors rely on the inherent stickiness of the silicone to silicone contact to maintain the relative positions of the catheter 2 and the collar 16. It is possible that this inherent stickiness may be compromised in an operating room environment. These are problems in want of a solution.

Summary of the Invention

A luer connector is described that is angled away from the patient's scalp in the direction of the drip assembly line. In the preferred embodiment, the luer connector has a female luer connector that mates with a male luer connector on the drip assembly line. The luer connector also has a hollow protrusion that extends into a catheter thereby allowing the luer connector to be fluidly connected to the catheter. A fluid passage is formed through the angled luer connector from the female luer connector, through the body of the angled luer connector and through the hollow protrusion. The luer connector has a pair of "wings" that extend outwardly from the luer connector and allow the luer connector to be sutured to the patient's scalp.

It is a primary object of the present invention to provide a luer connector for connecting a catheter to a drip assembly line that allows the medical practitioner to easily and reliably connect the drip assembly line to the catheter connector.

It is another object of the present invention to provide a luer connector for connecting a catheter to a drip assembly line that consolidates the features of a luer connector and a collar into a single unit.

These and other object of the present invention will be clear with reference to the description contained herein and more particularly with reference to the following detailed description of the invention and the accompanying drawings. Throughout the description, like elements are referred to by like reference numbers.

Brief Description of the Drawings

Figure 1 is a top view of a prior art collar and luer connector with the collar in an open position.

Figure 2 is a top view of the prior art collar and luer connector of Figure 2 with the collar of Figure 1 in a closed position around the catheter.

Figure 3 is a perspective view of the prior art collar and luer connector of Figure 2.

Figure 4 is a perspective view of the angled luer connector of the present invention.

Figure 5 is a side view of the angled luer connector of Figure 4.

Figure 6 is a cross-sectional side view of the luer connector of Figure 4.

Figure 7 is an end view of the angled luer connector of Figure 4.

Figure 8 is an end view of the angled luer connector of Figure 4.

Figure 9 is a bottom view of the angled luer connector of Figure 4.

Detailed Description of the Invention

The angled luer connector is shown in the Figures generally labeled 20. Angled luer connector 20 includes a central hollow barrel 22 having a barrel lumen 24. Barrel 22 has a barrel axis 26 that is coaxial with barrel lumen 24.

A hollow catheter connection protrusion 28 is attached to and extends away from barrel 22. Catheter connection protrusion 28 has a protrusion lumen 30 that extends through catheter connection protrusion 28. In the preferred embodiment, protrusion lumen 30 is coaxial with barrel lumen 24. Catheter connection protrusion 28 has an outside diameter that allows it to be firmly inserted into the inner lumen 10 of catheter 2. To more firmly seat catheter connection protrusion 28 within the inner lumen 10 of catheter 2, a bulbous end 32 is formed on the end of catheter connection protrusion 28. Bulbous end 32, at its greatest diameter, has a slightly larger diameter than the majority of catheter connection protrusion 28.

Angled luer connector 20 has a pair of substantially planar, wing-like anchoring protrusions 34a,b that extend away from barrel 22. Together, anchoring protrusions 34a,b form a substantially planar platform 36 to contact the patient's scalp 18. This prevents the angled luer connector 20 from rotating about the axis 26 and firmly locates the angled luer connector 20 on the patient's scalp 18. Each anchoring protrusion 34 has a suture

hole 38 that allows the anchoring protrusions 34a,b, and consequently the angled luer connector 20, to be firmly anchored to the patient's scalp 18.

A female luer connector 40 is attached to barrel 22 opposite protrusion 28. Female luer connector 40 has a female luer axis 42 that is not coaxial with axis 26. In the preferred embodiment, axis 42 intersects axis 26 at an angle of about 30°. The 30° angle between axis 42 and axis 26 is oriented so that axis 42 also forms about a 30° angle to the substantially planar platform 36. In this way, when angled luer connector 20 is sutured to a patient's scalp 18 as described below, female luer connector 40 is directed away from the patient's scalp 18.

In the preferred embodiment, female luer axis 42 is equidistant from each of the anchoring protrusions 34a,b. However, in an alternate embodiment, female luer axis 42 may be rotated around its intersection with barrel axis 26 so that it is closer to one of the anchoring projections 34a,b than the other.

Although the preferred angle between central axis 42 and axis 26 is about 30°, any angle between central axis 42 and axis 26 that allows female luer connector 40 to be directed away from the patient's scalp 18 is within the invention. In particular, it is anticipated that an angle as low as 15° or as high a 90° between central axis 42 and axis 26 is within the scope of the invention.

Female luer connector 40 is threaded and allows a male luer connector of corresponding threads to be mated with female luer connector 40 as is well understood in the art. Female luer connector 40 is in fluid communication with barrel lumen 24 so that fluid entering the female luer connector 40 through the interconnection between female

luer connector 40 and a male luer connector passes into barrel lumen 24. Because female luer connector 40 is angled away from the patient's scalp as described above, the physician will be able to more easily connect the male luer connector to the female luer connector 40.

Although the preferred embodiment has a female luer connector 40 connected to barrel 22, it is also within the scope of the invention for other connectors to be attached to barrel 22 for connecting angled luer connector 20 to a drip assembly line 4. This would include replacing female luer connector 40 with a male luer connector. Of course, a female luer connector would then need to be placed on the drip assembly line 4. Other connectors and connecting systems will occur to those skilled in the art.

Preferably, angled luer connector 20 is made of a rigid thermo-plastic such as polycarbonate, polypropylene, polyoxymethylene, PET, nylon, styrene or acrylic. Alternately, angled luer connector 20 can be made of metal, ceramic or almost any other semi-rigid thermo-plastic or thermoset material.

In use, a physician will insert catheter 2 into the patient's ventricle by performing a ventriculostomy. The proximal end of catheter 2 will extend outside of the patient's skull. The physician will insert catheter connection protrusion 28 into the inner lumen 10 of catheter 2. Bulbous end 32 assists in retaining catheter connection protrusion 28 in the inner lumen 10 of catheter 2. The physician will typically place a suture around catheter 2 and protrusion 28 to more securely hold catheter 2 in position on catheter connection protrusion 28.

Anchoring protrusions 34a,b are sutured to the patient's scalp 18 through suture holes 38. The male luer connector from the drip assembly line 4 is connected to female luer connector 40. Excess cerebrospinal fluid then passes from the ventricle, through the inner lumen 10 of catheter 2 to angled luer connector 20 where is passes to drip assembly line 4 to ultimately be collected and measured in drip assembly 6.

The invention has been described in connection with a specific embodiments. It will be clear to those skilled in the art that changes and modifications may be made to the description given herein and still fall within the scope of the invention as claimed in the following claims. Further, obvious modifications and changes to the description will occur to those skilled in the art that will still fall within the claims.

I claim:

1. A luer connector for connecting a catheter to a drip assembly comprising:

a hollow barrel having a barrel lumen, the barrel having a barrel axis that is coaxial with the barrel lumen;

a hollow catheter connection protrusion attached to and extending away from the barrel, the catheter connection protrusion having a protrusion lumen that extends through the catheter connection protrusion, the protrusion lumen being in fluid communication with the barrel lumen;

a pair of anchoring protrusions attached to and extending away from the barrel;

a female luer connector attached to the barrel opposite the catheter connection protrusion, the female luer connector having a female luer axis that is not coaxial with the barrel axis.

2. The luer connector of claim 1 wherein the female luer axis intersects the barrel axis at an angle of between 15° to 90°.

3. The luer connector of claim 2 wherein the female luer axis intersects the barrel axis at an angle of about 30°.

4. The luer connector of claim 1 wherein the pair of anchoring protrusions produce a substantially planar surface.

5. The luer connector of claim 4 wherein the female luer axis intersects the substantially planar surface.

6. The luer connector of claim 1 wherein the female luer axis is equidistant from each of the anchoring protrusions.

7. The luer connector of claim 1 wherein the female luer axis is closer to one of the anchoring protrusions than the other.

8. The luer connector of claim 1 wherein the anchoring protrusions each have a suturing hole to allow the anchoring protrusions to be attached to a patient.

9. The luer connector of claim 1 wherein the protrusion lumen is coaxial with the central lumen.

10. The luer connector of claim 1 wherein the protrusion has an outside diameter that of slightly larger diameter than the inner lumen of the catheter.

11. The luer connector of claim 1 further comprising a bulbous end formed on the end of the protrusion.

12. A luer connector for connecting a catheter to a drip assembly comprising:

a hollow barrel having a barrel lumen, the barrel having a barrel axis that is coaxial with the barrel lumen;

a hollow catheter connection protrusion attached to and extending away from the barrel, the catheter connection protrusion having a protrusion lumen that extends through the catheter connection protrusion, the protrusion lumen being in fluid communication with the barrel lumen;

a pair of anchoring protrusions attached to and extending away from the barrel, the pair of anchoring protrusions producing a substantially planar surface;

a female luer connector attached to the barrel opposite the catheter connection protrusion, the female luer connector having a female luer axis that is not coaxial with the barrel axis, the female luer axis intersecting the barrel axis at an angle of about 30°.

13. The luer connector of claim 12 wherein the female luer axis is equidistant from each of the anchoring protrusions.

14. The luer connector of claim 12 wherein the female luer axis is closer to one of the anchoring protrusions than the other.

15. The luer connector of claim 12 wherein the anchoring protrusions each have a suturing hole to allow the anchoring protrusions to be attached to a patient.

16. A luer connector for connecting a catheter to a drip assembly comprising:

a hollow barrel having a barrel lumen, the barrel having a barrel axis that is coaxial with the barrel lumen;

a hollow catheter connection protrusion attached to and extending away from the barrel, the catheter connection protrusion having a protrusion lumen that extends through the catheter connection protrusion, the protrusion lumen being in fluid communication with the barrel lumen;

a pair of anchoring protrusions attached to and extending away from the barrel, the pair of anchoring protrusions producing a substantially planar surface, each of the anchoring protrusions having a suturing hole to allow the anchoring protrusions to be attached to a patient;

a female luer connector attached to the barrel opposite the catheter connection protrusion, the female luer connector having a female luer axis that is not coaxial with the barrel axis, the female luer axis intersecting the barrel axis at an angle of about 30°.

17. The luer connector of claim 16 wherein the female luer axis is equidistant from each of the anchoring protrusions.

18. The luer connector of claim 16 wherein the female luer axis is closer to one of the anchoring protrusions than the other.

19. A connector for connecting a catheter to a drip assembly comprising:

a hollow barrel having a barrel lumen, the barrel having a barrel axis;

a hollow catheter connection protrusion attached to and extending away from the barrel, the catheter connection protrusion having a protrusion lumen that extends through the catheter connection protrusion, the protrusion lumen being in fluid communication with the barrel lumen;

means for attaching the luer connector to a patient's scalp;

means for fluidly connecting a drip assembly to the barrel opposite the catheter connection protrusion, the means for fluidly connecting having an axis that is not coaxial with the barrel axis.

20. A connector for connecting a catheter to a drip assembly comprising:

a first conduit having a first lumen, the first conduit having a first axis;

a second conduit having a second lumen, the second lumen in fluid communication with the first lumen, the second conduit having a second axis, the second axis intersecting the first axis but not being coaxial with the first axis;

means for connecting the first conduit to the catheter;

means for connecting the second conduit to the drip assembly; and

means for connecting the connector to a patient's scalp.

21. The connector of claim 20 wherein the second axis intersects the first axis at an angle of between 15° to 90°.

22. The connector of claim 21 wherein the second axis intersects the first axis at an angle of about 30°.

23. The connector of claim 20 wherein the means for connecting are a pair of anchoring protrusions extending away from the connector.

24. The connector of claim 23 wherein the pair of anchoring protrusions produce a substantially planar surface.

25. The connector of claim 24 wherein the second axis intersects the substantially planar surface.

26. The connector of claim 23 wherein the second axis is equidistant from each of the anchoring protrusions.

27. The connector of claim 23 wherein the second axis is closer to one of the anchoring protrusions than the other.

28. The connector of claim 23 wherein the anchoring protrusions each have a suturing hole to allow the anchoring protrusions to be attached to a patient.

Abstract of the Invention

A luer connector is described that is angled away from the patient's scalp in the direction of the drip assembly line. In the preferred embodiment, the luer connector has a female luer connector that mates with a male luer connector on the drip assembly line. The luer connector also has a hollow protrusion that extends into a catheter thereby allowing the luer connector to be fluidly connected to the catheter. A fluid passage is formed through the angled luer connector from the female luer connector, through the body of the angled luer connector and through the hollow protrusion. The luer connector has a pair of "wings" that extend outwardly from the luer connector and allow the luer connector to be sutured to the patient's scalp.

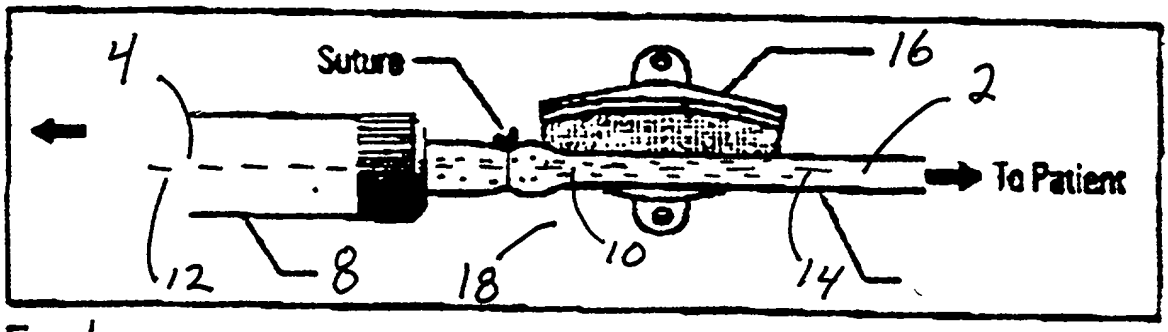

Fig. 1

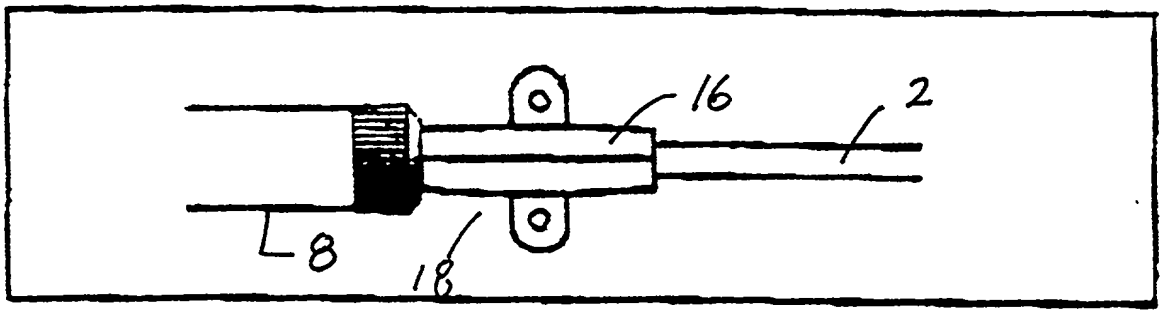

Fig. 2

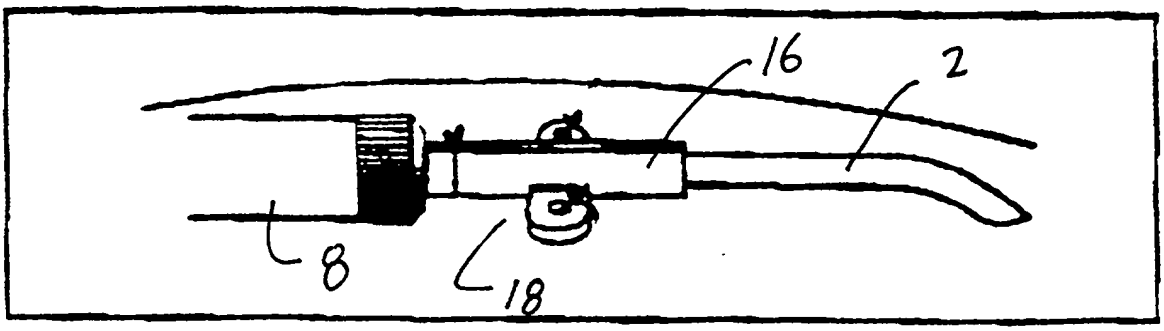

Fig. 3

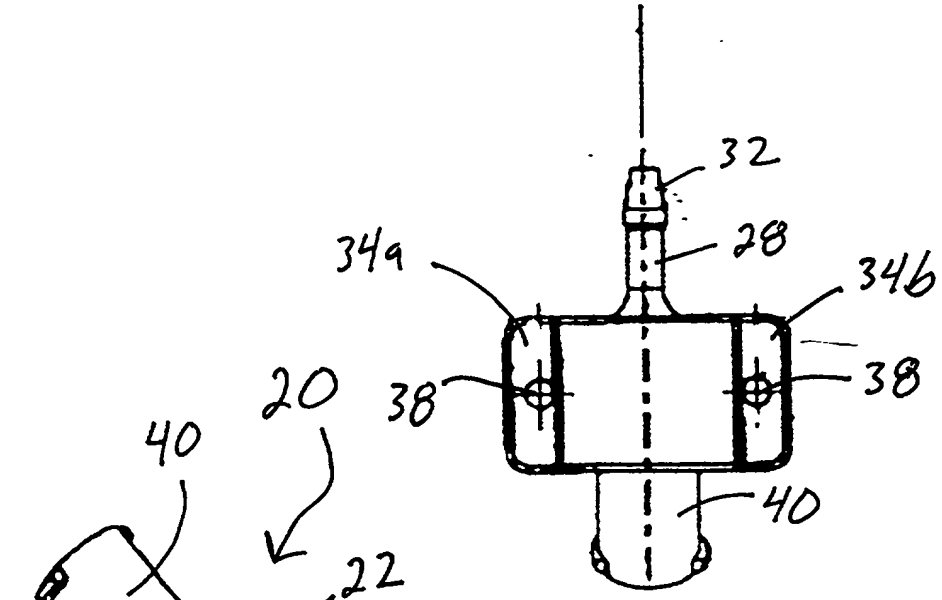

Fig. 9

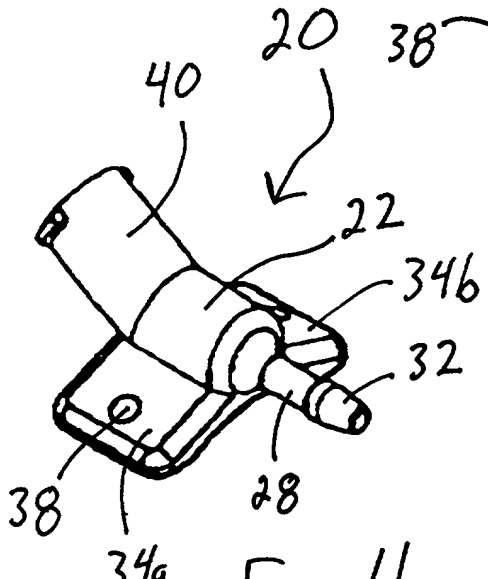

Fig. 4

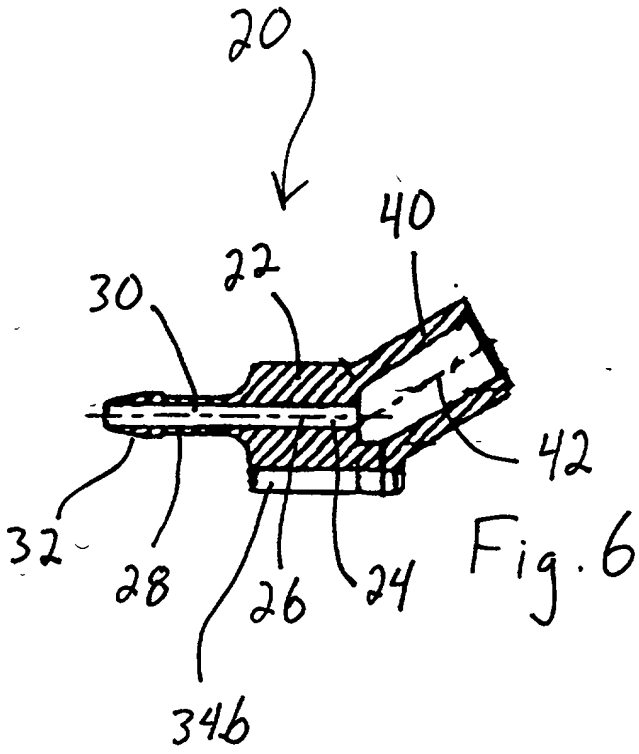

Fig. 6

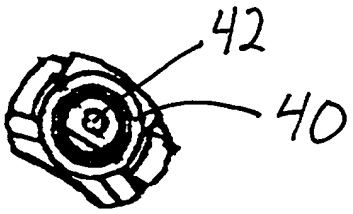

Fig. 8

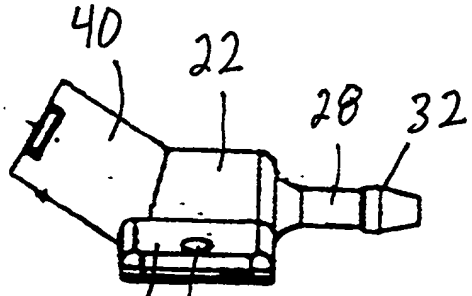

Fig. 5

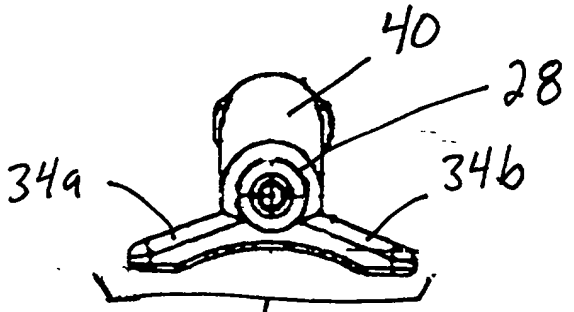

Fig 7

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United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **A Device Used to Connect an External Ventricular Drainage Catheter.**

The specification of which
a. X is attached hereto
b. _____ was filed on _____as application serial no. _____ and was amended on _____ (if applicable) (in the case of a PCT-filed application) described and claimed in international no. _____ filed _____ and as amended on _____ (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).[1]

I hereby claim foreign priority benefits under Title 35, United States Code, §119/365 of any foreign application(s) for patent of inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

a. X no such applications have been filed.
b. ___ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC §119

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

ALL FOREIGN APPLICATIONS, IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

I hereby claim the benefit under Title 35, United States Code, §1120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §156(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

---

[1] **§ 1.56 Duty of disclosure; fraud, striking or rejection of applications.**
(a) A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.

U.S. APPLICATION NUMBER	DATE OF FILING	STATUS (patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Harold R. Patton	Reg. No. 22,157	Michael B. Atlass	Reg. No. 30,606
Reed A. Duthler	Reg. No. 30,626	Michael J. Jaro	Reg. No. 34,472
Daniel W. Latham	Reg. No. 30,401	Dianne M.F. Plunkett	Reg. No. 35,649
Curtis D. Kinghorn	Reg. No. 33,926	Thomas F. Woods	Reg. No. 36,726
Peter Forrest	Reg. No. 33,235		

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2 0 1	Full Name of Inventor	FIRST NAME Derek	MIDDLE INITIAL J	LAST NAME Harper
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	Post Office Address	POST OFFICE ADDRESS 1268 Catrina Street	CITY Santa Ynez	STATE/ZIP/COUNTRY California 93460 USA
SIGNATURE OF INVENTOR 201				DATE

___ Additional pages for fourth and subsequent inventors attached.

_X_ This Declaration end with this page.